

Mark PAUSCH
Serial No. 08/816,011

Attorney Docket No. 8731.0007

Claims 1-33 and 36-39 are pending in this application. Claims 1-21, 23, 25, 26, 28, 31, 32, and 36-39 stand withdrawn from consideration as being directed to a non-elected invention.

Claims 22, 24, 27, 29, 30, and 33 are under prosecution.

Claims 22, 24, 27, 29, 30, and 33 have been amended. Support for these amendments can be found in the specification, as discussed below. Thus this amendment does not introduce new matter.

1. Sequence Rules 37 C.F.R. §§ 1.821-1.825

The Office asserts that this application does not comply with the requirements of 37 C.F.R. §§ 1.821-1.825. (Paper No. 35, p. 2.) Specifically, noting only SEQ ID NO:36, the Office asserts that the paper copy of the sequence listing does not appear to correspond with the submitted computer readable form (CRF) of the sequence listing. (*Id.*) In a later rejection, the Examiner notes that claim 24 recites the “nucleotide sequence of SEQ ID NO: . . . 36” and alleges this is confusing because SEQ ID NO:36 is an amino acid in the CRF. (*Id.* at 5.)

Applicants submitted a paper copy of the sequence listing, as well as a corresponding CRF, on October 15, 2001. SEQ ID NO:36 in both the paper copy and the CRF of the October 15, 2001, sequence listing is a nucleic acid sequence. Accordingly, Applicants do not understand the Office’s confusion. With the sequence listing submitted on October 15, 2001, Applicants respectfully submit that the requirements of 37 C.F.R. §§ 1.821-1.825 have been met. If the Examiner has any additional questions about the sequence listing, he is invited to contact Applicants’ representative.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

370058_1

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2. Rejection Under 35 U.S.C. § 101

The Office rejects claims 22, 24, 27, 29, 30, and 33 under 35 U.S.C. § 101, alleging that “the claimed invention is not supported by either a substantial asserted utility or a well established utility.” (Paper No. 35, p. 3.) The Office asserts that “[t]he specification as filed does not disclose or provide evidence that points to a property of the claimed two pore potassium channel such that another non-asserted utility would be well established. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a ‘real world’ context of use is required.” (*Id.*) Applicants respectfully traverse this rejection.

Applicants’ specification does teach one of skill in the art how to use Applicants’ potassium ion channels and the nucleic acids encoding them. Pages 33-38 of the specification disclose various substantial utilities for Applicants’ potassium ion channels. As one example, page 38 of the specification discloses that Applicants’ potassium ion channels can be used to selectively inhibit nematode pests by applying to such pests a compound capable of selectively inhibiting the activity of certain potassium ion channels. And pages 30-32 describe an exemplary yeast expression assay that permits high-throughput screening of compounds for their ability to selectively inhibit the activity of a potassium channel of interest. *See also*, Example 8 at pages 49-50.

As explained in the PTO’s own utility guidelines, “an assay method for identifying compounds that themselves have a ‘substantial utility’ define a ‘real world’ context of use.” (Revised Interim Utility Guidelines Training Materials, p. 6.) Based on Applicants’ disclosure, one of skill in the art could readily identify compounds that inhibit the activity of Applicants’

Mark PAUSCH
Serial No. 08/816,011

Attorney Docket No. 8731.0007

newly discovered potassium channels, including, for example, the *C. Elegans* potassium channel having the amino acid sequence of SEQ ID NO:63. Compounds identified in this way can be used, for example, to selectively inhibit nematode pests, as discussed in the specification. Therefore, consistent with the PTO's utility guidelines, Applicants' specification discloses an assay method for identifying compounds that have a "substantial utility" and, therefore, defines a "real world" use. Accordingly, Applicants respectfully request that this 35 U.S.C. § 101 rejection be withdrawn.

3. Rejections Under 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 22, 24, 27, 29, 30, and 33, under 35 U.S.C. § 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. (Paper No. 35, p.5.)

a. Claim 22

The Office rejects claim 22, asserting that the phrase "capable of encoding a protein designated CORK" is ambiguous. (*Id.*) Applicants have amended claim 22 to recite that "the nucleotide sequence encodes a protein comprising the amino acid sequence of SEQ ID NO:63." As provided in the Fourth Supplementary Preliminary Amendment dated January 28, 2002, SEQ ID NO:63 corresponds to the deduced amino acid sequence of a *C. Elegans* potassium channel (CORK). Accordingly, Applicants respectfully request withdrawal of this rejection.

b. Claim 24

The Office rejects claim 24, asserting that the recitation "nucleotide sequence of SEQ ID NO . . . 36" is confusing because SEQ ID NO:36 is an amino acid in the CRF. (*Id.*) As

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Serial No. 08/816,011

Attorney Docket No. 8731.0007

discussed above, In the paper copy and CRF of the sequence listing submitted October 15, 2001, SEQ ID NO:36 is a nucleotide sequence as recited in claim 24. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Office further rejects claim 24, asserting that the claim is ambiguous because it is drawn to “non-elected SEQ ID NO:1.” (*Id.*) Applicants note that the Restriction Requirement dated December 31, 2001, does not place SEQ ID NO:1 into any of the twelve restricted groups. Before removing SEQ ID NO:1 from claim 24, Applicants respectfully request clarification as to which group the Office has restricted this sequence.

Claim 24 was also rejected for reciting the term “hybridizes,” which the Office asserts “is a relative term whose metes and bounds are not clear.” (*Id.*) Applicants have amended claim 24 to more particularly point out the claimed invention. As amended, claim 24 recites high stringency conditions that can be used to determine whether the nucleotide sequence hybridizes to SEQ ID NO:1 or SEQ ID NO:36. Support for this amendment can be found in the specification, including, for example, at pages 20-21. Applicants have also amended this section of claim 24 to recite that the nucleotide sequence encodes a potassium channel having two pore-forming domains interposed between four transmembrane domains, where the first pore-forming domain comprises a peptide motif corresponding to SEQ ID NO:57. Support for this amendment can be found in the specification, including, for example, at pages 13-14. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Finally, the Office rejects claim 24 for reciting the term “functional derivative.” (*Id.*) The Office asserts that this term is ambiguous and its metes and bounds can not be determined

Mark PAUSCH
Serial No. 08/816,011

Attorney Docket No. 8731.0007

because the term is allegedly "not limited by structure or function." Applicants respectfully assert that in view of the specification one of ordinary skill in the art would have been reasonably apprised of the meaning of the term "functional derivative" in the context of the claimed invention. As explained in the specification, "the term 'functional derivative' is used to define any DNA sequence which is derived from the original DNA sequences^[1] and which still possesses at least one of the biological activities present in the parent molecule." (Specification, p. 17.) In an effort to expedite prosecution, however, Applicants have amended claim 24 to recite a "functional derivative comprising at least 40% homology to the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO:36." Support for this amendment can be found in the specification, including, for example, at page 18, which describes modified nucleic acids having varying degrees of homology to the disclosed potassium channel sequences. As explained in the specification, these modified sequences maintain the biological activity of the unmodified sequences. And in the case of nucleic acid sequences, the proteins expressed therefrom at least substantially maintains the biological activity. Applicants respectfully request withdrawal of this rejection.

c. Claim 27

The Office rejects claim 27 for depending from non-elected claim 16. (*Id.*) Applicants have amended claim 27 to depend from elected claim 22 obviating this rejection.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

1 In the case of claim 24, this refers to SEQ ID NO:1 and SEQ ID NO:36.
370058_1

Mark PAUSCH
Serial No. 08/816,011

Attorney Docket No. 8731.0007

d. Claim 29

The Office rejects claim 29 asserting that expression vectors are not capable of expressing potassium channels in a cell membrane. (*Id.*) Applicants have amended claim 29 to recite a vector comprising the nucleotide sequence of claim 24. Accordingly, Applicants respectfully request that this rejection be withdrawn.

e. Claim 33

The Office rejects claim 33 because it depends from non-elected claim 32, which is directed to a method and not a nucleic acid, as recited in claim 33. (*Id.* at 6.) Applicants have amended claim 33 to depend from elected claims 22 or 24, thereby obviating this rejection.

4. Rejections Under 35 U.S.C. § 112, First Paragraph (Written Description)

The Office rejects claims 22, 24, 27, 29, 20, and 33 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. (Paper No. 35, p. 6.) According to the Office, one of skill in the art cannot envision the full genus of molecules encompassed by the claimed nucleic acid molecules. (*Id.*) The Office also characterized the “essential feature” of the invention as “the nucleic acid molecule which encodes a CORK two pore potassium channel of SEQ ID NO:36.” (*Id.*) Applicants do not agree with the Office’s characterization of Applicants’ invention.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
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Applicants have amended claims 22 and 24.² As amended, claim 22 recites that the nucleotide sequence encodes a protein comprising the amino acid sequence of SEQ ID NO:63 and is supported by the written description of Applicants' specification, including, for example, pages 59-50 (Example 14) and Figures 9A and 9B. Claim 24 recites that the hybridizing nucleotide sequence encodes a potassium channel having two pore-forming domains interposed between four transmembrane domains, where the first pore-forming domain comprises a peptide motif corresponding to SEQ ID NO:57. In addition, claim 24 recites that the functional derivative has at least 40% homology to the nucleotide sequence of SEQ ID NO:1 and SEQ ID NO:36. Thus, claim 24 recites structural features common to the members of the claimed genus of nucleic acids.

As recognized by the Federal Circuit:

A description of a genus of cDNAs may be achieved by means of a recitations of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus **or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.**

Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) (emphasis added); *see also*, M.P.E.P. § 2163, p. 2100-164 (8th Ed. August 2001). Applicants respectfully assert that the structural features recited in claim 24 are sufficient to show that Applicants were in possession of the claimed genus at the time the application was filed. Accordingly, Applicants respectfully request that this 35 U.S.C. § 112, first paragraph, rejection be withdrawn.

2 Claims 27, 29, 30, and 33 depend directly or indirectly from claims 22 or 24.
370058_1

Mark PAUSCH
Serial No. 08/816,011

Attorney Docket No. 8731.0007

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and timely allowance of the pending claims.

If there are any fees due in connection with the filing of this paper not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By:  Reg. No. 43,592 for:
Matthew T. Latimer
Reg. No. 44,024

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Tel: (202) 408-4495
Fax: (202) 408-4400
Email: matthew.latimer@finnegan.com

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

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APPENDIX

IN THE CLAIMS:

22. (Amended) An isolated nucleotide sequence, [capable of encoding] wherein the nucleotide sequence encodes a protein [designated CORK] comprising the amino acid sequence of SEQ ID NO:63.

24. (Twice Amended) An isolated nucleotide sequence comprising:
(i) the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO:36;
(ii) a nucleotide sequence that hybridizes to said sequence of SEQ ID NO: 1 or SEQ ID NO:36 under high stringency conditions, wherein said high stringency conditions comprise hybridization conditions comprising 50% formamide and 5X SSPC at 50°C and washing conditions comprising 0.5X SSPC at 60°C, and wherein said nucleotide sequence encodes a potassium channel, wherein said potassium channel comprises a first pore-forming domain interposed between a first and a second transmembrane helix and a second pore-forming domain interposed between a third and a fourth transmembrane helix, and wherein the first pore-forming domain comprises SEQ ID NO:57, wherein

X at positions 1, 4, and 5 are T or S;

X at position 6 is I or V; and

X at position 8 is V, L, Y, F, M, or I;

(iii) a nucleotide sequence that is degenerate to the nucleotide sequence of SEQ ID NO: 1 or SEQ ID NO:36; or

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Attorney Docket No. 8731.0007

(iv) a functional derivative comprising at least 40% homology to [of] the nucleotide sequence of SEQ ID NO: 1 or SEQ ID NO:36.

27. (Amended) [An expression] A vector [capable of expressing the potassium channel of Claim 16 in a cell membrane of a yeast cell] comprising the nucleic acid of Claim 22.

29. (Twice Amended) [An expression] A vector [capable of expressing the potassium channel encoded by] comprising the nucleotide sequence of Claim 24 [in a cell membrane of a yeast cell].

30. (Amended) A transformed yeast cell comprising the [expression] vector of Claim 27.

33. (Amended) A kit comprising the nucleotide sequences of Claim [32] 22 or Claim 24.

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HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
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Fax 202.408.4400
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